INTERIM RECOMMENDATIONS FOR COLLECTING CLINICAL SPECIMENS FROM PERSONS FOR CORONAVIRUS DISEASE 2019 (COVID-19)

All testing for SARS-CoV-2 should be conducted in consultation with a healthcare provider (HCP).

The alternative recommendations below by the Food & Drug Administration (FDA) are made in the context of limited quantities of testing supplies during this public health crisis. The information is being provided to help address availability concerns regarding certain critical components of COVID-19 diagnostic tests during this pandemic.

Specimen Collection

A nasopharyngeal (NP) specimen is the preferred choice for swab-based SARS-CoV-2 testing. If a nasopharyngeal specimen is not available, then any of the following are acceptable:

- oropharyngeal (OP) specimen collected by HCP;
- mid-turbinate specimen (MTS) by onsite self-collection or HCP (using a flocked tapered swab); or
- anterior nares nasal swab (NS) specimen by onsite self-collection or HCP (using a round foam swab).

https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

Multiple specimens may be taken with a single swab. If a separate swab is used for collecting specimens from two different locations in the same patient, both swabs may be placed in the same vial in order to conserve collection and assay supplies. At this time, anterior nares and mid-turbinate specimen collection are only appropriate for symptomatic patients and both nares should be swabbed. For patients with productive cough, a sputum sample is an acceptable lower respiratory specimen.

FDA believes that sample collection with a flocked swab, when available, is preferred. Collection should be conducted with a sterile swab. If the applicator handle requires additional trimming, the trimming should be performed with a sterile pair of scissors to prevent contamination of the sample. Swab recommendations are based on limited available evidence, and expert opinion suggests further research is needed in this area. Calcium alginate swabs or swabs with wooden shafts are not recommended by the Centers for Disease Control & Prevention (CDC), as they may contain substances that inactivate some viruses and inhibit PCR testing.

FDA believes that it would still be appropriate for laboratories to accept specimens collected in a sub-optimal manner for analysis and note the circumstances on the report (e.g. with a swab for which there is less evidence of effectiveness). These specimens may have decreased sensitivity, so caution should be exercised when interpreting negative results.

Transport Media

Viral Transport Media/Universal Transport Media (VTM/UTM) remain the preferred transport media. In the absence of VTM/UTM, alternative transport media can be used to collect and transport patient samples for molecular RT-PCR SARS-CoV-2 assays. These recommendations apply to swab-based specimen collection by healthcare providers (HCP), and to anterior nares (nasal) and mid-turbinate specimen collection onsite by self-collection. The best available evidence indicates that these transport media will stabilize the SARS-CoV-2 RNA without meaningful degradation.

Laboratories can create their own viral transport media. Refer to CDC's SOP#: DSR-052-01: Preparation of Viral Transport Media. Specimens can be stored for up to 72 hours at 4°C.

https://www.cdc.gov/coronavirus/2019-ncov/downloads/Viral-Transport-Medium.pdf

Liquid Amies media may be used for viral transport when universal transport media is not available. Specimens can be stored in liquid Amies media for up to 72 hours at 4°C.

Other solutions may also be used for viral transport when universal transport media is not available. FDA recommends use of phosphate buffered saline (PBS), including molecular grade PBS when available, and other similar formulations including Delbecco's PBS, to collect and transport samples for molecular RT-PCR SARS-CoV-2 assays. If PBS is not available, normal saline may be used. FDA believes that a sterile glass or plastic vial containing between 1mL and 3mL of PBS or normal saline is appropriate. Specimens can be stored up to 72 hours at 4°C.

There are limited data available on test performance with specimens which have been frozen in any transport media; therefore, specimen stability should be investigated if freezing is necessary.

Shipping

Specimens must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulationsexternal iconexternal iconexternal icon. Store specimens at 2-8°C and ship overnight on ice pack. Additional useful and detailed information on packing, shipping, and transporting specimens can be found at Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19).

Sources:

1. *CDC: Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)*
2. *FDA: FAQs on Diagnostic Testing for SARS-CoV-2*

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